

EPA REG. No. 83933-2

21-Day Screen Completed by
Contractor

21-Day Expires on 4/26/13

Jacket # 83933-E

MRID# 490969

Content Screen: Recommend to Pass/**Fail**

11-3 Review: **Pass**/**Fail**/NA

Overall Status: Recommend to Pass/**Fail**

Transfer This Jacket to:

Jacqueline Campbell-McFarlane

DATA PACKAGE BEAN SHEET

Date: 14-May-2013

Page 1 of 3

Decision #: 477373

DP #: (411779)

PRIA

Parent DP #:

Submission #: 933363

E-Sub #:

*** Registration Information ***

Registration: 83933-E - BIOGUARD TRI-BOR PASTE

Company: 83933 - PRESCHEM PTY. LTD

Risk Manager:

Risk Manager Reviewer: Thomas Luminello, Jr. TLUMINEL

Sent Date:

PRIA Due Date: 07-Oct-2013

Edited Due Date:

Type of Registration: Product Registration - Section 3

Action Desc: (A540) NEW PRODUCT;NON-FAST TRACK;FIFRA SEC. 2(MM) USES;

Ingredients: See page 3

*** Data Package Information ***

Expedite: ☒ Yes ☐ No

Date Sent: 14-May-2013

Due Back:

DP Ingredient: See page 3

DP Title: Product Chemistry

CSF Included: ☒ Yes ☐ No

Label Included: ☒ Yes ☐ No

Parent DP #:

Assigned To

Date In

Date Out

Organization: AD / PSB

Last Possible Science Due Date: 07-Sep-2013

Team Name: CTT

Science Due Date:

Reviewer Name:

Sub Data Package Due Date:

Contractor Name:

*** Studies Sent for Review ***

Printed on Page 2

*** Additional Data Package for this Decision ***

No Additional Data Packages

*** Data Package Instructions ***

New Product Registration: Tri-bor Paste

Technical Screen: Due date: 6/6/2013

Please review the CSF and product chemistry data for completeness.

Contains Zinc Borate - please determine if particulate matter/nano is an issue

Data Review

Please review the CSF and data for acceptability, MRID 49096901 thru 49096907

MRID	MRID Status	Citation Reference	Guideline	86-5 Status
49096901		Smith, F. (2013) Bioguard Tri-Bor Paste: Product Identity and Composition, Description of Beginning Materials, Formulation Process, Discussion of Formation of Impurities, and Certified Limits. Unpublished study prepared by SciReg, Inc. 46p.	830.1550/Product Identity and composition	Pass (24-Apr-2013)
49096901		Smith, F. (2013) Bioguard Tri-Bor Paste: Product Identity and Composition, Description of Beginning Materials, Formulation Process, Discussion of Formation of Impurities, and Certified Limits. Unpublished study prepared by SciReg, Inc. 46p.	830.1600/Description of materials used to produce the product	Pass (24-Apr-2013)
49096901		Smith, F. (2013) Bioguard Tri-Bor Paste: Product Identity and Composition, Description of Beginning Materials, Formulation Process, Discussion of Formation of Impurities, and Certified Limits. Unpublished study prepared by SciReg, Inc. 46p.	830.1650/Description of formulation process	Pass (24-Apr-2013)
49096901		Smith, F. (2013) Bioguard Tri-Bor Paste: Product Identity and Composition, Description of Beginning Materials, Formulation Process, Discussion of Formation of Impurities, and Certified Limits. Unpublished study prepared by SciReg, Inc. 46p.	830.1670/Discussion of formation of impurities	Pass (24-Apr-2013)
49096901		Smith, F. (2013) Bioguard Tri-Bor Paste: Product Identity and Composition, Description of Beginning Materials, Formulation Process, Discussion of Formation of Impurities, and Certified Limits. Unpublished study prepared by SciReg, Inc. 46p.	830.1750/Certified limits	Pass (24-Apr-2013)
49096902		Smith, F. (2013) Bioguard Tri-Bor Paste: Analytical Method. Unpublished study prepared by SciReg, Inc. 8p.	830.1800/Enforcement analytical method	Pass (24-Apr-2013)
49096903		Smith, F. (2013) Bioguard Tri-Bor Paste: Summary of the Physical-Chemical Properties Test Guidelines. Unpublished study prepared by SciReg, Inc. 6p.	830.6302/Color	Pass (24-Apr-2013)
49096903		Smith, F. (2013) Bioguard Tri-Bor Paste: Summary of the Physical-Chemical Properties Test Guidelines. Unpublished study prepared by SciReg, Inc. 6p.	830.6303/Physical state	Pass (24-Apr-2013)
49096903		Smith, F. (2013) Bioguard Tri-Bor Paste: Summary of the Physical-Chemical Properties Test Guidelines. Unpublished study prepared by SciReg, Inc. 6p.	830.6304/Odor	Pass (24-Apr-2013)
49096903		Smith, F. (2013) Bioguard Tri-Bor Paste: Summary of the Physical-Chemical Properties Test Guidelines. Unpublished study prepared by SciReg, Inc. 6p.	830.7000/pH	Pass (24-Apr-2013)
49096903		Smith, F. (2013) Bioguard Tri-Bor Paste: Summary of the Physical-Chemical Properties Test Guidelines. Unpublished study prepared by SciReg, Inc. 6p.	830.7200/Melting point/melting range	Pass (24-Apr-2013)
49096903		Smith, F. (2013) Bioguard Tri-Bor Paste: Summary of the Physical-Chemical Properties Test Guidelines. Unpublished study prepared by SciReg, Inc. 6p.	830.7300/Density/relative density	Pass (24-Apr-2013)
49096904		Santos, E. (2013) Physical State, Appearance, Color and Odor: Bioguard Tri-Bor: Final Report. Project Number: 2262/FIS/089/11. Unpublished study prepared by Bioensaïos Analises e Consultoria Ambiental Ltda. 8p.	830.6302/Color	Pass (24-Apr-2013)
49096904		Santos, E. (2013) Physical State, Appearance, Color and Odor: Bioguard Tri-Bor: Final Report. Project Number: 2262/FIS/089/11. Unpublished study prepared by Bioensaïos Analises e Consultoria Ambiental Ltda. 8p.	830.6303/Physical state	Pass (24-Apr-2013)
49096904		Santos, E. (2013) Physical State, Appearance, Color and Odor: Bioguard Tri-Bor: Final Report. Project Number: 2262/FIS/089/11. Unpublished study prepared by Bioensaïos Analises e Consultoria Ambiental Ltda. 8p.	830.6304/Odor	Pass (24-Apr-2013)

DATA PACKAGE BEAN SHEET

Date: 14-May-2013

Page 1 of 3

Decision #: 477373

DP #: (411780)

PRIA

Parent DP #:

Submission #: 933363

E-Sub #:

*** Registration Information ***

Registration: 83933-E - BIOGUARD TRI-BOR PASTE

Company: 83933 - PRESICHEM PTY. LTD

Risk Manager:

Risk Manager Reviewer: Thomas Luminello, Jr. TLUMINEL

Sent Date:

PRIA Due Date: 07-Oct-2013

Edited Due Date:

Type of Registration: Product Registration - Section 3

Action Desc: (A540) NEW PRODUCT;NON-FAST TRACK;FIFRA SEC. 2(MM) USES;

Ingredients: See page 3

*** Data Package Information ***

Expedite: ☒ Yes ☐ No

Date Sent: 14-May-2013

Due Back:

DP Ingredient: See page 3

DP Title: Acute Toxicology

CSF Included: ☒ Yes ☐ No

Label Included: ☒ Yes ☐ No

Parent DP #:

Assigned To

Date In

Date Out

Organization: AD / PSB

Last Possible Science Due Date: 07-Sep-2013

Team Name: CTT

Science Due Date:

Reviewer Name:

Sub Data Package Due Date:

Contractor Name:

*** Studies Sent for Review ***

Printed on Page 2

*** Additional Data Package for this Decision ***

Can be printed on its own page

*** Data Package Instructions ***

New Product Registration: Tri-Bor Paste

TECHNICAL SCREEN DUE DATE: 6/6/2013

Please review the acute tox. 6 pack for completeness

DATA REVIEW

Please review the data for acceptability

DP#: (411780)

*** Studies Sent for Review ***

Decision#: (477373)

MRID	MRID Status	Citation Reference	Guideline	86-5 Status
49096908	-	Medeiros, M. (2012) Acute Oral Toxicity for Rats: Bioguard Tri-Bor: Final Report. Project Number: 2262/RAA/099/11. Unpublished study prepared by Bioensaïos Analises e Consultoria Ambiental Ltda. 15p.	870.1100/Acute Oral Toxicity	Pass (24-Apr-2013)
49096909		Medeiros, M. (2012) Acute Dermal Toxicity in Rats: Bioguard Tri-Bor: Final Report. Project Number: 2262/RAC/100/11. Unpublished study prepared by Bioensaïos Analises e Consultoria Ambiental Ltda. 13p.	870.1200/Acute dermal toxicity	Pass (24-Apr-2013)
49096910		Smith, F. (2013) Bioguard Tri-Bor Paste: Acute Inhalation Toxicity Waiver Request. Unpublished study prepared by SciReg, Inc. 42p.	870.1300/Acute inhalation toxicity	Pass (24-Apr-2013)
49096911		Medeiros, M. (2012) Acute Eye Irritation / Corrosion in Rabbits: Bioguard Tri-Bor: Final Report. Project Number: 2262/IOP/102/11. Unpublished study prepared by Bioensaïos Analises e Consultoria Ambiental Ltda. 12p.	870.2400/Acute eye irritation	Pass (24-Apr-2013)
49096912		Medeiros, M. (2012) Rabbit Acute Dermal Irritation/Corrosion: Bioguard Tri-Bor: Final Report. Project Number: 2262/ICP/103/11. Unpublished study prepared by Bioensaïos Analises e Consultoria Ambiental Ltda. 12p.	870.2500/Acute dermal irritation	Pass (24-Apr-2013)
49096913		Medeiros, M. (2012) Evaluation of the Skin Sensitisation in Guinea Pigs: Buehler Test Method: Bioguard Tri-Bor: Final Report. Project Number: 2262/SCCMB/101/11. Unpublished study prepared by Bioensaïos Analises e Consultoria Ambiental Ltda. 16p.	870.2600/Skin sensitization	Pass (24-Apr-2013)

Material Sent for Data Extraction

Reg. # 83933-2

Description: _____

☐ Material(s) Sent to Data Extraction Contractors:

☐ New Stamped Label Dated _____

☒ Notification Dated 12-31-13

☐ New CSF(s) Dated _____

☐ Other: _____

☐ Decision #: _____

☐ Other Action/Comments: _____

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Tom Luminello

Phone: 308-8075 Division: AD

Date: _____

JAN 2 2014



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

December 31, 2013

Patricia Biggio, Agent for
Preschem Pty. Ltd.
c/o Sci Reg, Inc.
12733 Director's Loop
Woodbridge, VA 22192

Subject: Bioguard Tri-Bor Paste
EPA Registration Number: 83933-2
Application Date: December 4, 2013
Receipt Date: December 4, 2013

Dear Ms. Biggio:

This acknowledges receipt of your Notification submitted in accordance with the provisions of Pesticide Registration (PR) Notice 98-10 under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) section 3(c)9.

Proposed Notification

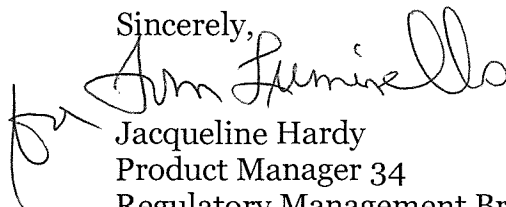
Add graphic illustrating the proper lifting technique when picking up product container.

General Comments

Based on a review of the material submitted, the Notification is acceptable.

Should you have any questions about this letter, please contact Tom Luminello at (703) 308-8075.

Sincerely,

A handwritten signature in black ink, appearing to read "Tom Luminello", is written over the typed name.

Jacqueline Hardy
Product Manager 34
Regulatory Management Branch II
Antimicrobials Division (7510 P)

SciReg, Inc.
Science and Regulatory Consultants

December 4, 2013

Ms. Jacqueline Hardy
Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S. Crystal Dr.
Arlington, VA 22202

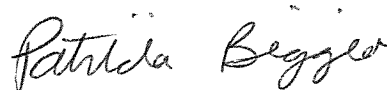
Re: Bioguard Tri-Bor Paste (EPA Reg No. 83933-2)
Notification consistent with PR Notice 98-10

Dear Ms. Hardy:

On behalf of Preschem Pty. Ltd., SciReg, Inc. is submitting a notification consistent with PR Notice 98-10 to add a symbol to the label which illustrates proper lifting technique. Two copies of the label, one with the changes clearly marked, are included.

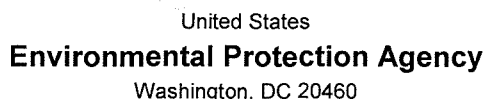
Should you have any questions, please contact me at (703) 494-6500 or pbiggio@SciReg.com.

Sincerely,



Patricia Biggio
Regulatory Specialist

Enclosures



United States

	Registration
	Amendment
X	Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 83933-2	2. EPA Product Manager J. Hardy	3. Proposed Classification <input checked="checked" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Bioguard Tri-Bor Paste	PM# 34	
5. Name and Address of Applicant <i>(Include ZIP Code)</i> Preschem Pty. Ltd. 147-149 Herald Street Cheltenham, Victoria 3192 Australia <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____

Section - II

☐ Amendment - Explain below.
 ☐ Final printed labels in response to Agency letter dated _____

☐ Resubmission in response to Agency letter dated _____
 ☐ "Me Too" Application.

☒ Notification - Explain below.
 ☐ Other - Explain below.

Notification to add symbol per PR Notice 98-10

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input checked="" type="checkbox"/> Other (Specify) _____ carboard with heat-sealed LDPE liner	
* Certification must be submitted		If "Yes" Unit Packaging wgt. _____ No. Per Container _____		If "Yes" Package wgt _____ No. Per Container _____			
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container				4. Size(s) Retail Container 10.1 oz, 20.2 oz, 10 lbs, 22 lbs, 44 lbs		5. Location of Label Directions <input checked="" type="checkbox"/> On label. <input type="checkbox"/> On label accompanying product.	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled				<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)

Name	Title	Telephone No. (Include Area Code)
Patricia Biggio	Agent	(703) 494-6500

Certification

I certify that the statements which I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature <i>Patricia Biggio</i>	3. Title Agent (SciReg, Inc.)
4. Typed Name Patricia Biggio	5. Date <i>04 Dec 2013</i>

Highlighted Copy



Bioguard Tri-Bor Paste

FOR INDUSTRIAL USE.

NOT FOR HOUSEHOLD USE.

FIRST AID	
IF IN EYES	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently for 15-20 minutes.• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.• Call a Poison Control Center or doctor for treatment advice.
IF ON SKIN OR CLOTHING	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.• Call a Poison Control Center or doctor for treatment advice.
IF SWALLOWED	<ul style="list-style-type: none">• Call a Poison Control Center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to do so by a Poison Control Center or doctor.• Do not give anything to an unconscious person.
<p>IN CASE OF EMERGENCY, CALL CHEMTREC AT 800-424-9300. Have the product container or label with you when calling a Poison Control Center or doctor or going for treatment.</p> <p>NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.</p>	

Active Ingredients:

Boron sodium oxide, pentahydrate	45%
Boric acid.....	10%
Zinc borate.....	5%

Other Ingredients:..... 40%

TOTAL: 100%

KEEP OUT OF REACH OF CHILDREN

CAUTION

See Side Panel for Additional Precautionary Statements.

EPA Reg. No. 83933-2 EPA Est. No. 83933-AUS-001

BATCH NO.:

Net Contents:

- | | | |
|---------------------------------|----------------------------------|----------------------------------|
| <input type="checkbox"/> 44 lbs | <input type="checkbox"/> 10 lbs | <input type="checkbox"/> 20.2 oz |
| <input type="checkbox"/> 22 lbs | <input type="checkbox"/> 10.1 oz | |

Bioguard Tri-Bor Paste

DESCRIPTION

Bioguard Tri-Bor Paste has a total of 60% active ingredients for preservation of timber. The paste is a combination of three boron active ingredients, which effectively diffuses through timber. Bioguard Tri-Bor Paste can be used above or below ground in situations where timbers are susceptible to wood-decaying fungi.

Bioguard Tri-Bor Paste is commonly used for groundline treatment of utility poles worldwide, and for other applications such as railroad ties, protection of posts, timber bridges and other timber structures that become susceptible to decay.

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION. Causes moderate eye irritation. Harmful if swallowed or if absorbed through skin. Avoid contact with skin, eyes or clothing. Wear goggles, face shield, or safety glasses. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

ENVIRONMENTAL HAZARDS
This pesticide is toxic to fish and wildlife. Do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwaters or rinsate.

PHYSICAL OR CHEMICAL HAZARDS

Do not use or store near heat or open flame.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling

UTILITY POLES-External Application:

Bulk Paste Application

After inspection, apply Bioguard Tri-Bor Paste with a brush or trowel directly onto the timber. Apply to achieve a layer of no less than 1/16 inch thick to the required distance above and below groundline. Typical applications are from 18 inches to 24 inches below ground to 3 inches above groundline. Ensure paste is pushed into uneven surfaces on the pole such as cracks and checks. Additional below ground coverage may be required where a pole has been exposed near a roadway or hillside. The paste is then covered with a water-proof bandage. If more than one bandage is required,

overlap ends to ensure complete coverage. Wrap bandage tightly, stapling or nailing to keep it in place. Back fill and tamp soil firmly, but do not fill above the bandage.

Pre-formed Bandage Application

Apply pre-formed Bioguard Tri-Bor bandages directly to the pole surface. No brushing or toweling of paste is required. Unroll a section of bandage and cut to a length approximately 1 inch longer than the circumference of the pole. Remove the thin film from the back of the bandage and wrap the bandage around the pole in the same location as described above for the bulk paste method. The bandage will stick to the pole surface; however, it will require gentle hand pressure to achieve proper adherence before backfilling.

TIMBER STRUCTURES-Internal Application

For control of internal decay, apply Bioguard Tri-Bor Paste into holes where protection is required using the smallest pack size and a grease/caulking gun. Following application, it is important to cap holes with a plug.

RAILROAD TIES-External Application

Apply Bioguard Tri-Bor Paste manually or with a simplified mechanical application machine. Typical applications include the application of the paste under the tie plate to achieve a layer no less than 1/16 inch in thickness. Ensure the paste penetrates uneven surfaces, checks, and the predrilled holes of the spikes or screws that hold the tie plate in place. Minimizing the biological deterioration of wood around anchoring hardware ensures longevity for the tie, reduces loosening of the tie plate, resulting in widening of the rail.

OTHER WOODEN STRUCTURES

Apply paste to area requiring protection from decay using a minimum thickness of 1/16 inch and always ensure a protective bandage is secured over the paste to prevent interference.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

PESTICIDE STORAGE: Do not store near open heat or flame.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL: Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available, or puncture and dispose of in sanitary landfill, or by incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

MANUFACTURED BY:

Preschem Pty. Ltd.
147-149 Herald St.
Cheltenham, 3192, Victoria
Australia
www.preschem.com



TASK ASSIGNMENT FORM
Antimicrobial Division/Regulatory Management Branches

ORIGINATOR/PRODUCT REVIEWER: <i>T. Lumine/10</i>					RMB II TEAM <u>34</u>		
Decision No: <i>486305</i>		Submission No: <i>944545</i>			EPA File Symbol/Reg No. <i>83933-2</i>		
PRIA Fee: \$ _____		Action Code: <i>332</i>					
GPRA:	FQPA	Non-FQPA			Product Re-reg.		
PRIA:	ME-TOO	New Use <input type="checkbox"/>	Old Chemical	New Chemical <input type="checkbox"/>	Amend w/data		
		MONTH	DAY	YEAR			
APPLICATION DATE		<i>12</i>	<i>4</i>	2013			
EPA PIN DATE		<i>12</i>	<i>4</i>	2013			
DATE PM RECEIVED FROM FRONT END				2013			
DATE SENT TO SCIENCE				2013			
DATE RECEIVED FROM SCIENCE							
NEGOTIATED DUE DATE				DATE DUE OUT OF AGENCY		<i>1/3/2014</i>	
Type of Data:	PSB Product Chemistry	PSB Acute Toxicology	PSB Efficacy	RASSB Environmental Fate	RASSB Ecological Effects	RASSB Chronic Toxicology	RASSB Exposure/Residue

Comments: Please provide hard and electronic copy of deliverable(s).

NOTIFICATION PLS review label. Registrant is adding graphic to demonstrate proper lifting Technique

Receipt for Section 3

S: 944545

Resubmission: ☐ Yes ☒ No

Regulatory Type: Product Registration - Section 3

Fee For Service: ☐ Yes ☒ No

Application Type: Notification

Print Letter

Enter More Information

Tracking

Company: 83933 PRESICHEM PTY. LTD

V

Risk Manager: Antimicrobials Division, Risk Management Team 34

Product #: 83933-2

Product Name: BIOGUARD TRI-BOR PASTE

Override#:

Me Too Section3:

Me Too Product Name:

Application Date: 04-Dec-2013

OPP Rec'd Date: 04-Dec-2013

Front End Date: 05-Dec-2013

Risk Manager Send Date: 05-Dec-2013

FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

Notification consistent with PR Notice 98-10

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:

Receipt Content

Des

Paper Label

View/Edit

New Ingredient Request Date:

New Ingredient Received Date:

Material Sent for Data Extraction

Reg. # 83933-2

Description: New registration

☒ Material(s) Sent to Data Extraction Contractors:

☒ New Stamped Label Dated 9-11-13

☐ Notification Dated _____

☒ New CSF(s) Dated 9-10

☐ Other: _____

☐ Decision #: _____

☐ Other Action/Comments: _____

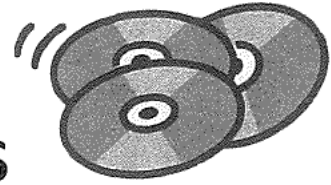
File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Tam Luminello

Phone: 308-8075 Division: AD

Date: SEP 23 2013

NEW APPLICATIONS



DATE: APR - 5 2013

FILE REG NUMBER: 83 933- E

FEP (OPPIN ENTRY) LV APR - 8 2013

(Initial & Date)

FILE ROOM: _____

(Initial & Date)

SIG: _____

(Initial & Date)

FILE ROOM: _____

(Initial & Date)

ASSIGN TO PM: AD 34 RD _____ BPPD _____

_____ JACKET TO SHELF (DATA)



U.S. ENVIRONMENTAL PROTECTION
AGENCY

Office of Pesticide Programs
Antimicrobials Division (7510-P)
1200 Pennsylvania Avenue N.W.
Washington, D.C. 20460

NOTICE OF PESTICIDE:

☒ Registration
☐ Reregistration

(under FIFRA, as amended)

EPA Reg. Number:

83933-2

Date of
Issuance:

Sept. 11, 2013

Term of Issuance:

Unconditional

Name of Pesticide Product:

**Bioguard Tri-Bor
Paste**

Name and Address of Registrant (include ZIP Code):

Frederick T. Smith, U.S. Agent of Record for Preschem Pty. Ltd.
c/o SciReg, Inc.
12733 Director's Loop
Woodbridge, VA. 22192

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Antimicrobials Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product (OPP Decision No. 477373) is unconditionally registered in accordance with FIFRA sec 3(c)(7)(A) provided that you:

1. Submit and/or cite all data required for registration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and, submit acceptable responses required for re-registration of your product under FIFRA section 4.
2. Change EPA File Symbol 83933-E to EPA Registration Number 83933-2.
3. You must submit acceptable product specific Corrosion Characteristics and Storage Stability data within a year of this Registration Notice.

Copies of our science reviews of your Product Chemistry and Acute Toxicology data are enclosed.

Submit one copy of the finished final printed label prior to releasing this product for sale.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e).

Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the unconditionally approved label is enclosed for your records.

Signature of Approving Official:


Jacqueline Hardy

Product Manager 34
Regulatory Management Branch II
Antimicrobials Division (7510-P)

Sept. 11, 2013

Bioguard Tri-Bor Paste

FOR INDUSTRIAL USE.

NOT FOR HOUSEHOLD USE.

FIRST AID	
IF IN EYES	<ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a Poison Control Center or doctor for treatment advice.
IF ON SKIN OR CLOTHING	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a Poison Control Center or doctor for treatment advice.
IF SWALLOWED	<ul style="list-style-type: none"> • Call a Poison Control Center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by a Poison Control Center or doctor. • Do not give anything to an unconscious person.
<p>IN CASE OF EMERGENCY, CALL CHEMTREC AT 800-424-9300. Have the product container or label with you when calling a Poison Control Center or doctor or going for treatment.</p> <p>NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.</p>	

Active Ingredients:

Boron sodium oxide, pentahydrate..... 45%
 Boric acid 10%
 Zinc borate 5%

Other Ingredients: 40%

TOTAL: 100%

KEEP OUT OF REACH OF CHILDREN

CAUTION

See Side Panel for Additional Precautionary Statements.

EPA Reg. No. 83933-2

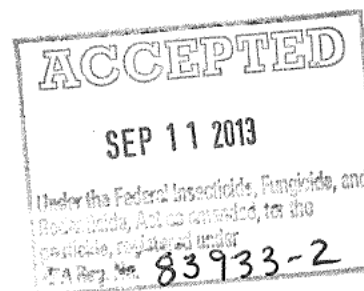
EPA Est. No. 83933-AUS-001

Preschem Pty. Ltd.
 147-149 Herald St.
 Cheltenham, 3192, Victoria
 Australia

BATCH NO.:

Net Contents:

☐ 44 lbs ☐ 10 lbs ☐ 20.2 oz ☐
☐ 22 lbs ☐ 10.1 oz



Sept. 11, 2013

Bioguard Tri-Bor Paste

DESCRIPTION

Bioguard Tri-Bor Paste has a total of 60% active ingredients for preservation of timber. The paste is a combination of three boron active ingredients, which effectively diffuses through timber. Bioguard Tri-Bor Paste can be used above or below ground in situations where timbers are susceptible to wood-decaying fungi.

Bioguard Tri-Bor Paste is commonly used for groundline treatment of utility poles worldwide, and for other applications such as railroad ties, protection of posts, timber bridges and other timber structures that become susceptible to decay.

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION. Causes moderate eye irritation. Harmful if swallowed or if absorbed through skin. Avoid contact with skin, eyes or clothing. Wear goggles, face shield, or safety glasses. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish and wildlife. Do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwaters or rinsate.

PHYSICAL OR CHEMICAL HAZARDS

Do not use or store near heat or open flame.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling

UTILITY POLES-External Application:

Bulk Paste Application

After inspection, apply Bioguard Tri-Bor Paste with a brush or trowel directly onto the timber. Apply to achieve a layer of no less than 1/16 inch thick to the required distance above and below groundline. Typical applications are from 18 inches to 24 inches below ground to 3 inches above groundline. Ensure paste is pushed into uneven surfaces on the pole

such as cracks and checks.

Additional below ground coverage may be required where a pole has been exposed near a roadway or hillside. The paste is then covered with a water-proof bandage. If more than one bandage is required, overlap ends to ensure complete coverage. Wrap bandage tightly, stapling or nailing to keep it in place. Back fill and tamp soil firmly, but do not fill above the bandage.

Pre-formed Bandage Application

Apply pre-formed Bioguard Tri-Bor bandages directly to the pole surface. No brushing or toweling of paste is required. Unroll a section of bandage and cut to a length approximately 1 inch longer than the circumference of the pole. Remove the thin film from the back of the bandage and wrap the bandage around the pole in the same location as described above for the bulk paste method. The bandage will stick to the pole surface; however, it will require gentle hand pressure to achieve proper adherence before backfilling.

TIMBER STRUCTURES-Internal Application

For control of internal decay, apply Bioguard Tri-Bor Paste into holes where protection is required using the smallest pack size and a grease/caulking gun. Following application, it is important to cap holes with a plug.

RAILROAD TIES-External Application

Apply Bioguard Tri-Bor Paste manually or with a simplified mechanical application machine. Typical applications include the application of the paste under the tie plate to achieve a layer no less than 1/16 inch in thickness. Ensure the paste penetrates uneven surfaces, checks, and the predrilled holes of the spikes or screws that hold the tie plate in place. Minimizing the biological deterioration of wood around anchoring hardware ensures longevity for the tie, reduces loosening of the tie plate, resulting in widening of the rail.

OTHER WOODEN STRUCTURES

Apply paste to area requiring protection from decay using a minimum thickness of 1/16 inch and always ensure a protective bandage is secured over the paste to prevent interference.

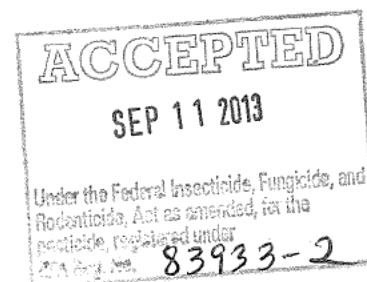
STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

PESTICIDE STORAGE: Do not store near open heat or flame.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL: Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available, or puncture and dispose of in sanitary landfill, or by incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

June 19, 2013

MEMORANDUM

SUBJECT: Acute Toxicity Review for EPA Reg. No.: 83933-E
DP Barcode: D411780

FROM: Chris Jiang, Chemist
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

Chris Jiang
6/19/13

THRU: Karen Hicks, Team Leader
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

KRH

TO: Jacqueline Campbell\Thomas Luminello, Jr.
Regulatory Management Branch II
Antimicrobials Division (7510P)

Applicant: Preschem Pty., Ltd.

FORMULATION FROM LABEL:

Active Ingredient(s):

Boron sodium oxide, pentahydrate

45 %

Boric acid

10 %

Zinc borate

5 %

Other Ingredient(s):

40 %

Total:

100 %

u 6/21/13

BACKGROUND: The registrant has submitted an acute toxicity package to register this wood preservative product. The package includes a label, a Confidential Statement of Formula, an acute oral study (MRID 49069608), an acute dermal study (MRID 49069609), a waiver for acute inhalation (MRID 49069610) based on the form of the product, a primary eye irritation study (MRID 49069611), a primary skin irritation study (MRID 49069612), and a dermal sensitization study (MRID 49069613).

FINDINGS:

1. The waiver request for acute inhalation toxicity is **granted**. The product is a thick paste with the consistency of peanut butter and is sold in this form. In this form, it is unlikely that a gas, aerosol, or vapor can be generated. Thus, there is minimal likelihood of inhalation exposure to the product. If the product were diluted to allow for generation of a respirable atmosphere, the product would no longer be representative of that to which the user would be exposed.

2. The acute toxicity profile for 83933-E is:

Study	MRID Number	Toxicity Category	Study Status
Acute Oral Toxicity	49069608	III	Acceptable
Acute Dermal Toxicity	49069609	III	Acceptable
Acute Inhalation Toxicity	49069610	IV	Waiver Granted
Primary Eye Irritation	49069611	III	Acceptable
Primary Skin Irritation	49069612	IV	Acceptable
Dermal Sensitization	49069613	Nonsensitizer	Acceptable

LABELING

1. The signal word is **CAUTION**.

2. The precautionary labeling must read, "Causes moderate eye irritation. Harmful if swallowed or absorbed through skin. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse."

3. The first aid statements must read:

If in eyes:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- Call a poison control center or doctor for treatment advice.

If on skin:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

If swallowed:

- Call a poison control center or doctor immediately for treatment advice.
- Have a person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a poison control center or doctor
- Do not give anything by mouth to an unconscious person.

4. The following first aid statements are optional:

If inhaled:

- Move person to fresh air.
- If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.

DATA REVIEW FOR ACUTE ORAL TOXICITY TESTING (81-1, 870.1100)

Product Manager: Jacquie Campbell
MRID No.: 49069608

Reviewer: Chris Jiang
Final Report Date: December 5, 2012
Study No.: 2262-RAA-099-11

Testing Laboratory: Bioensaios Analises e Consultoria Ambiental
Study Director: Maria Lucia Schiaffino Medeiros

Quality Assurance (40 CFR 160.12): A statement of GLP compliance was included.

Test Material: Bioguard Tri-Bor, lot 1A 1012, liquid using corn oil as the vehicle
Dosage: 2000 mg/kg

Species: Two sets of female Wistar rats

Age: Sixty days at study start

Weight: 268 to 286 grams for first stage at study start; 131 to 145 for second stage at study start

Source: Animais de Laboratorio Criacao e Comercial Ltda

Conclusions:

- 1. LD₅₀ (mg/kg):** LD₅₀ > 2000 mg/kg
- 2. The estimated LD₅₀ is greater than 2000 mg/kg.**
- 3. Toxicity Category:** III **Classification:** Acceptable

Procedure (Deviations from 81-1): The Acute Toxic Class Method was used. Females were used because they are typically more sensitive than males. During the study, temperature fell below the recommended range. These deviations had no impact on the integrity of the study.

Results:

Reported Mortality

Animal Number	Dosage (mg/kg)	Short-Term Outcome	Long-Term Outcome
1	2000	O	O
2	2000	O	O
3	2000	O	O

Animal Number	Dosage (mg/kg)	Short-Term Outcome	Long-Term Outcome
1	2000	O	O
2	2000	O	O
3	2000	O	O

O = lived, X = died

Observations: All animals were active and healthy through the study.

Gross Necropsy Findings: Gross necropsies were unremarkable.

DATA REVIEW FOR ACUTE DERMAL TOXICITY TESTING (81-2, 870.1200)

Product Manager: Jacquie Campbell
MRID No.: 49069609

Reviewer: Chris Jiang
Final Report Date: December 5, 2012
Study No.: 2262-RAA-100-11

Testing Laboratory: Bioensaios Analises e Consultoria Ambiental
Study Director: Maria Lucia Schiaffino Medeiros

Quality Assurance (40 CFR 160.12): A statement of GLP compliance was included.

Test Material: Bioguard Tri-Bor, lot 1A 1012, liquid
Dosage: 2000 mg/kg

Species: Five male and five female Wistar rats

Age: Sixty days at study start

Weight: ♀: 229 to 276 grams at study start; ♂: 348 to 464 grams at study start

Source: Animais de Laboratorio Criacao e Comercial Ltda

Conclusions:

- 1. LD₅₀ (mg/kg):** LD₅₀ > 2000 mg/kg
- 2. The estimated LD₅₀ is greater than 2000 mg/kg.**
- 3. Toxicity Category:** III **Classification:** Acceptable

Procedure (Deviations from 81-2): No deviations occurred during the study.

Results:

Reported Mortality

Dosage (mg/kg)	(Number Deaths/Number Tested)		
	Males	Females	Combined
2000	0/5	0/5	0/10

Observations: All animals were active and healthy through the study.

Gross Necropsy Findings: Gross necropsies were unremarkable.

DATA REVIEW FOR PRIMARY EYE IRRITATION TESTING (81-4, 870.2400)

Product Manager: Jacquie Campbell
MRID No.: 49069611

Reviewer: Chris Jiang
Final Report Date: December 5, 2012
Study No.: 2262-IOP-102-11

Testing Laboratory: Bioensaios Analises e Consultoria Ambiental
Study Director: Maria Lucia Schiaffino Medeiros

Quality Assurance (40 CFR 160.12): A statement of GLP compliance was included.

Test Material: Bioguard Tri-Bor, lot 1A 1012, liquid
Dosage: 0.1 g

Species: Three female New Zealand rabbits
Age: Three months at study start
Weight: 2.072 to 3.384 kg at study start
Source: Roberto Pegoraro, Feliz, RS

Summary:

- Toxicity Category:** III
- Classification:** Acceptable

Procedure (Deviations from 81-4): During the study, temperature rose above the recommended range. This deviation had no impact on the integrity of the study.

Results:

Individual Scores for Ocular Irritation

Rabbit number	1 (Female)					2 (Female)					3 (Female)				
Time after treatment (hours)	1	24	48	72	168	1	24	48	72	168	1	24	48	72	168
I. Corneal Opacity	0	1	0	0	0	0	1	0	0	-	0	1	0	0	-
II. Iritis	2	2	2	1	0	2	0	0	0	-	2	1	0	0	-
Conjunctivae															
A. Hyperemia	2	1	1	0	0	1	0	0	0	-	1	1	0	0	-
B. Edema	2	0	0	0	0	1	0	0	0	-	1	0	0	0	-
C. Secretion	2	1	1	1	0	2	1	0	0	-	3	1	0	0	-

Fluorescein was used after the 24-hour observation

DATA REVIEW FOR PRIMARY SKIN IRRITATION TESTING (81-5, 870.2500)

Product Manager: Jacquie Campbell

Reviewer: Chris Jiang

MRID No.: 49069612

Final Report Date: December 13, 2012

Study No.: 2262-ICP-103-11

Testing Laboratory: Bioensaios Analises e Consultoria Ambiental

Study Director: Maria Lucia Schiaffino Medeiros

Quality Assurance (40 CFR 160.12): A statement of GLP compliance was included.

Test Material: Bioguard Tri-Bor, lot 1A 1012, liquid

Dosage: 0.5 g moistened in water

Species: Three female New Zealand rabbits

Age: Three months at study start

Weight: 1.354 to 2.401 kg at study start

Source: Roberto Pegoraro, Feliz, RS

Summary:

1. **Toxicity Category:** IV
2. **Classification:** Acceptable

Procedure (Deviations from 81-5): During the study, temperature rose above the recommended range. This deviation had no impact on the integrity of the study.

Results:

Animal number	Erythema and eschar formation/edema after unwrap (Time after patch removal)					
	1 hr	24 hrs	48 hrs	72 hrs	7 days	14 days
1-F	1/0/0	1/0/0	0/0/0	0/0/0	-	-
2-F	1/0/0	1/0/0	0/0/0	0/0/0	-	-
3-F	1/0/1	1/0/0	1/0/0	1/0/0	1/1/0	0/0/0

DATA REVIEW FOR DERMAL SENSITIZATION TESTING (81-6, 870.2600)

Product Manager: Jacquie Campbell

Reviewer: Chris Jiang

MRID No.: 49069613

Final Report Date: December 5, 2012

Study No.: 2262-SCCMB-102-11

Testing Laboratory: Bioensaios Analises e Consultoria Ambiental

Study Director: Maria Lucia Schiaffino Medeiros

Quality Assurance (40 CFR 160.12): A statement of GLP compliance was included.

Test Material: Bioguard Tri-Bor, lot 1A 1012, liquid

Positive Control: 2-mercaptobenzothiazole

Species: Guinea pigs

Weight: 312 to 444 grams at study start

Age: Ninety days at study start

Source: Laboratory Animals Creation and Trade Ltd

Method: Buehler Method

Summary:

- 1. This Product is not a dermal sensitizer.**
- 2. Classification:** Acceptable

Procedure (Deviation From §81-6): During the study, temperature rose above the recommended range. This deviation had no impact on the integrity of the study.

Procedure: After preliminary tests, the definitive study was undertaken. Once each week for three weeks, either the undiluted test material or nothing was applied to the clipped side of each animal using gauze patches which were held in place by an occlusive bandage. After the exposure period, the bandages were removed and discarded. The guinea pigs were scored at 24 and at 48 hours after each induction.

Fourteen days after the third induction, all animals were challenged with 50% test substance in Tween 80 on the opposite flank. The guinea pigs were scored at 24 and at 48 hours after challenge.

Results: At 24 hours after the first induction, five animals had patchy erythema. At 48 hours after the first induction, one guinea pig was observed to have patchy erythema. At 24 hours after the second induction, two guinea pigs had patchy erythema. At 48 hours after the second induction, no response was observed. At 24 hours after the third induction, two animals had patchy erythema. At 48 hours after the third induction, one animal was observed to have patchy erythema.

At 24 hours and at 48 hours after challenge, no response was observed.

The historical positive control showed appropriate results.

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460**



United States
Environmental Protection
Agency

Office of Pesticide Programs

Antimicrobials Division (AD)

September 10, 2013

EPA Reg#: 83933-E		DP Barcode: 411779	
		Submission #: 933363	
Product name: Bioguard Tri-Bor Paste		Registrant: Preschem PTY. LTD	
Reviewer's name: Juan F. Negrón		AD/PSB/CTT- Product Chemistry Review	
Agency due date: 10/07/13		PSB received date: 05/15/13	
CTT received date: 05/15/13		Science due date: 08/13/13	
Formulation type: EUP		Sub data package due date: 08/23/13	
Integrated system: <input type="checkbox"/>	Non integrated system: <input checked="" type="checkbox"/>	Food use: <input type="checkbox"/>	Non food use: <input checked="" type="checkbox"/>
Action Code: A540	Date Completed: 09/10/13	Guideline: 830 Groups A & B	
PC Code	CAS #	Active Ingredient Names	% wt (label)
011110	11130-12-4	Boron sodium oxide, pentahydrate	45
Molecule structure (optional):			
$\text{HO}-\text{B}(\text{OH})_3 \cdot \text{Na}^+ \left[\text{H}_2\text{O} \right]_5$			
011001	10043-35-3	Boric acid	10
Molecule structure (optional):			
$\text{HO}-\text{B}(\text{OH})_3$			
128859	138265-88-0	Zinc borate	5
Molecule structure (optional):			
$\text{BH}_3 \cdot \text{Zn}^{2+} \left[\text{H}_2\text{O} \right]_{15} \text{O}^{2-}$			
$\text{BH}_3 \cdot \text{Zn}^{2+} \text{O}^{2-}$			
MRID(s):49096900, 49096901, 49096902, 49096903, 49096904, 49096905, 49096906, 49096907			
Approver: Karen P. Hicks		Approved date: 09/10/13	

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



United States
Environmental Protection
Agency

Office of Pesticide Programs

Antimicrobials Division (AD)

September 10, 2013

MEMORANDUM

Subject: Product Chemistry Review for EPA Reg # 83933-E.
Product name: Bioguard Tri-Bor Paste
DP #411779

From: Juan F. Negrón, Chemist
Product Science Branch, CT Team
Antimicrobials Division (7510P)

Thru: Karen P. Hicks, CT Team Leader
Product Science Branch
Antimicrobials Division (7510P)

A handwritten signature in black ink, appearing to read "K. P. Hicks".

To: Jacqueline Campbell / Thomas Luminello, Jr.
PM Team 34

APPLICANT: Preschem PTY. LTD
Action code: A540
Due date: 10/07/13

Product Formulation
Active Ingredient

% by wt.

Boron sodium oxide, pentahydrate	45
Boric acid	10
Zinc borate	5

BACKGROUND:

On behalf of the registrant, Preschem PTY. LTD, the consultant, SciReg, Inc., is submitting a new product registration application for Bioguard Tri-Bor Paste. The product is a remedial wood preservation product for industrial use. The end-use product can be used above or below ground in situations where timbers are susceptible to wood-decaying fungi. The Product Chemistry Reviewer has reviewed the following documents:

- A letter, dated 04/05/13; MRID # 49096900.
- A draft label pin punched on 04/05/13.
- A Transmittal document, dated 04/05/13.
- A Formulator's Exemption Statement, dated 04/05/13.
- A Confidential Statements of Formula (CSFs), dated 04/17/13, 05/16/13, & 09/10/13, for the basic formulation.
- A study titled "Bioguard Tri-Bor Paste: Product Identity and Composition, Description of Beginning Materials, Formulation Process, Discussion of Formation of Impurities, and Certified Limits," dated 04/03/13, Volume 2 MRID # 49096901.
- A study titled "Bioguard Tri-Bor Paste: Analytical Method," dated 04/01/13, Volume 3 MRID # 49096902.
- A study titled "Bioguard Tri-Bor Paste: Summary of the OPPTS 830 Series Physical-Chemical Properties Test Guidelines," Volume 4 MRID # 49096903.
- A study titled "Final Report Physical state, appearance, color and odor Bioguard Tri-Bor," dated 01/11/13 Volume 5 MRID # 49096904.
- A study titled "Final Report pH determination Bioguard Tri-Bor," dated 01/11/13 Volume 6 MRID # 49096905.
- A study titled "Final Report Melting point Bioguard Tri-Bor," dated 01/11/13 Volume 7 MRID # 49096906.
- A study titled "Final Report Density determination Bioguard Tri-Bor," Volume 8 MRID # 49096907.

FINDINGS:

1. The OPPTS 830 Groups A & B guidelines for product chemistry data requirements applicable to end-use products have been met, with the exception of the OPPTS 830.6317 Storage Stability and OPPTS 830.6320 Corrosion Characteristic guidelines.
2. The CSFs, dated 04/17/13 & 05/16/13, for the basic formulation are obsolete.
3. The CSF, dated 09/10/13, for the basic formulation is revised.
4. The CSF and the label have the same nominal concentration for all three active ingredients (AIs).
5. The registrant has indicated that the OPPTS 830.1900 Submittal of samples is not applicable because the product is not an integrated system (see MRID # 49096903). The registrant updated the rationale by indicating that "Sample is available upon request."

CONCLUSIONS:

The CSF, dated 09/10/13, for the basic formulation is acceptable. The OPPTS 830 Groups (A & B) product chemistry data requirements applicable to end-use products have been met, with the exception of the OPPTS 830.6317 Storage Stability and OPPTS 830.6320 Corrosion Characteristic guidelines. These guidelines are in progress. See table below.

PRODUCT CHEMISTRY REVIEW

I. CONFIDENTIAL STATEMENT OF FORMULA

a. Type of formulation and source registration:

- Non-integrated formulation system ☒
- Are all TGAIs used registered? Yes ☐ No ☐
- Integrated formulation system ☐
- If "ME-TOO," specify EPA Reg. No. of existing product:

b. Clearance of inert ingredients for non-food use:

Yes ☒ No ☐ NA ☐

c. Physical state of product: solid - paste

d. The chemical IDs and analytical information (including that for the TGAIs), density, pH, and flammability are consistent with that given in 830 Series, Group B.

Yes ☒ No ☐

e. The NCs and CLs are acceptable.

Yes ☒ No ☐

f. Active ingredients	<u>NC</u> (%)	<u>LCL</u> (%)	<u>UCL</u> (%)
Boron sodium oxide, pentahydrate	45	43.65	46.35
Boric acid	10	9.50	10.50
Zinc borate	5	4.75	4.75

- Do all impurities of toxicological significance have a UCL?
Yes ☐ No ☐ Not applicable ☒
- Have all impurities of $\geq 0.1\%$ in the product been identified?
Yes ☐ No ☐ Not applicable ☒

II PRODUCT LABEL

- a. The active ingredients statement (chemical IDs and NC) is consistent with the CONFIDENTIAL STATEMENT OF FORMULA. Yes ☒ No ☐
- b. The formula contains one of the following:
- 10% or more of a petroleum distillate: Yes ☐ No ☒
 - 1.0% or more of methyl alcohol: Yes ☐ No ☒
 - sodium nitrite at any level: Yes ☐ No ☒
 - a toxic List 1 inert at any level: Yes ☐ No ☒
 - arsenic in any form: Yes ☐ No ☒
- c. If “yes” to any of the above, does the inert ingredients statement contain a footnote indicating this? Yes ☐ No ☐ Not applicable ☒
- d. Appropriate warning statement(s) regarding flammability or explosive characteristics of the product are listed on the label. Yes ☐ No ☐ Not applicable ☒
- e. The storage and disposal instructions for the pesticide container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses. Yes ☐ No ☐
- f. The product requires an expiration date at which time the NC falls below the LCL (based on the 1-year storage stability data or other information). Yes ☐ No ☐
- In progress.

Table A:
Product Chemistry (Series 830, Group A)

Data Requirements	Acceptance of Information	MRID No.
830.1550 Product Identity ¹	A	49096901
830.1600 Description of Materials	A	49096901
830.1620 Production Process ²	A	49096901
830.1650 Formulation Process ³	A	49096901
830.1670 Formation of Impurities ⁴	A	49096901
830.1700 Preliminary Analysis ⁵	NR Not required – product is a non-integrated system.	
830.1750 Certified Limits ⁶	A	49096901
830.1800 Enforcement Analytical Method ⁷	A	49096902
830.1900 Submittal of Samples	N (The product is not produced by an integrated formulation system).	49096903
	A Available upon request.	

Explanation: A=acceptable; N=not acceptable; NA=technically not applicable; NR=not required); G=data gap; U=requires upgrading; W=waived; E=EPA estimate.

¹See Confidential Appendix A for additional information.

²For MP/EP products produced by an integrated formulation system.

³For products from a TGAI or MP.

⁴May be waived unless actual/possible impurities are of toxicological concern.

⁵Five batch analysis required for products produced by an integrated formulation system.

⁶If different from standard CLs recommended in 40 CFR 158.175, this should be discussed in Confidential Appendix A.

⁷Abbreviate method used as follows: gas chromatography (GC), infrared (IR), ultraviolet absorption (UV), nuclear magnetic resonance (NMR), etc.

Table B:
Physical and Chemical Characteristics (Series 830, Group B)

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
830.6302 Color	A	Black (see also 49096904).	49096903
830.6303 Physical State	A	Semi – solid (paste)	49096903
830.6304 Odor	A	Characteristic odor (see also 49096904)	49096903
830.6313 Stability to Normal and Elevated Temperatures, Metals, and Metal Ions	NR	<i>[Not required for end-use products.]</i>	49096903
830.6314 Oxidation/Reduction; Chemical Incompatibility	A	The product does not contain an oxidizing or reducing agent.	49096903
830.6315 Flammability/ Flame Extension	A	The product does not contain combustible liquids.	49096903
830.6316 Explodability	A	The product is not potentially explosive.	49096903
830.6317 Storage Stability	A	In progress.	49096903
830.6319 Miscibility ¹	A	The product is not an emulsifiable liquid that will be diluted with petroleum solvents.	49096903
830.6320 Corrosion Characteristics	A	In progress.	49096903
830.6321 Dielectric Breakdown Voltage	A	Not to be use around electrical equipment.	49096903
830.7000 pH ²	A	8.9 (1% solution) @ 20.9 °C (see also 49096905)	49096903
830.7050 UV/Visible Absorption	NR	<i>[Not required for end-use products.]</i>	
830.7100 Viscosity	A	The product is not a liquid.	49096903
830.7200 Melting Point/Melting Range	NR	<i>[Not required for end-use products.]</i> However, it was reported as >330 °C	49096903
830.7220 Boiling Point/Boiling Range	NR	<i>[Not required for end-use products.]</i>	
830.7300 Density/Relative Density/Bulk Density	A	1.3132 g/cm ³ @19.5 °C. (see also 49096907)	49096903
830.7370 Dissociation Constants in Water	NR	<i>[Not required for end-use products.]</i>	
830.7550/830.7560/830.7570 Partition Coefficient	NR	<i>[Not required for end-use products.]</i>	49096903
830.7840/830.7860 Water Solubility	NR	<i>[Not required for end-use products.]</i>	49096903
830.7950 Vapor Pressure	NR	<i>[Not required for end-use products.]</i>	

Product ingredient source information may be entitled to confidential treatment

SciReg, Inc.
Science and Regulatory Consultants

49096900

April 5, 2013

Ms. Jacqueline Campbell
Document Processing Desk (APPL)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S. Crystal Dr.
Arlington, VA 22202

Re: New Product Registration Application
Bioguard Tri-Bor Paste
Preschem Pty. Ltd. (Co. No. 83933)

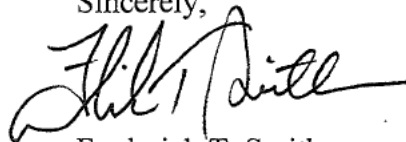
Dear Ms. Campbell:

On behalf of Preschem Pty. Ltd., SciReg, Inc. is submitting a new product registration application for Bioguard Tri-Bor Paste, a remedial wood preservation product for industrial use. This product contains three active ingredients: 1) boron sodium oxide, pentahydrate (PC Code 11110); 2) boric acid (PC Code 11001); and 3) zinc borate (PC Code 128859). The boron sodium oxide, pentahydrate and boric acid are from EPA-registered sources. For zinc borate, [REDACTED]

This regulatory action falls under PRIA Category A540: New end use product, FIFRA §2(mm) uses. Preschem qualifies for a 75% PRIA fee reduction. Supporting company and financial documentation are attached, as is their fee payment receipt.

Should you have any questions, please let me know.

Sincerely,



Frederick T. Smith
Senior Regulatory Specialist

Enclosures

TRANSMITTAL DOCUMENT

Submitter

Preschem Pty. Ltd.
147-149 Herald St.
Cheltenham, 3192, Victoria
Australia

SciReg, Inc.*
12733 Director's Loop
Woodbridge, VA 22192

*SciReg, Inc. is the authorized agent for Preschem Pty. Ltd.

Regulatory action in support of which this package is submitted

New Product Registration:
Bioguard Tri-Bor Paste

Transmittal Date

April 5, 2013

Contents

Vol. 1 Administrative Materials

49096901 Vol. 2 Product Identity and Composition, Description of Beginning Materials, Formulation Process, Discussion of Formation of Impurities and Certified Limits (OPPTS 830.1550, 830.1600, 830.1650, 830.1670, 830.1750)

49096902 Vol. 3 Analytical Method (OPPTS 830.1800)

49096903 Vol. 4 Physical-Chemical Properties Summary

49096904 Vol. 5 Physical-Chemical Properties (OPPTS 830.6302, 830.6303, 830.6304)

49096905 Vol. 6 Physical-Chemical Properties (OPPTS 830.7000)

49096906 Vol. 7 Physical-Chemical Properties (OPPTS 830.7200)

49096907 Vol. 8 Physical-Chemical Properties (OPPTS 830.7300)

49096908 Vol. 9 Acute Oral Toxicity (OPPTS 870.1100)

49096909 Vol. 10 Acute Dermal Toxicity (OPPTS 870.1200)

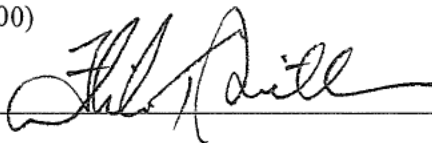
49096910 Vol. 11 Acute Inhalation Toxicity (OPPTS 870.1300)

49096911 Vol. 12 Eye Irritation (OPPTS 870.2400)

49096912 Vol. 13 Dermal Irritation (OPPTS 870.2500)

49096913 Vol. 14 Dermal Sensitization (OPPTS 870.2600)

Company Official: Frederick T. Smith



Company Name: SciReg, Inc.

Company Contact: Frederick T. Smith (703) 494-6500

Jiang, Chris

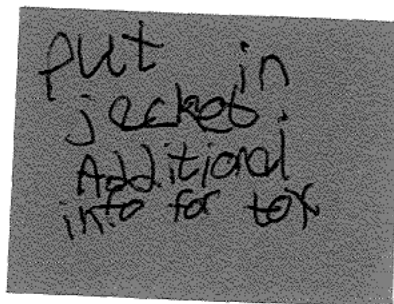
From: Fred Smith [fsmith@SciReg.com]
Sent: Monday, June 17, 2013 9:01 AM
To: Jiang, Chris
Subject: Tri-Bor Paste

Chris—

As follow up to our telephone call on Friday regarding the Tri-Bor dermal sensitization study, below is the information from the laboratory that shows the quantity of Tri-Bor used in the definitive assay and the quantity of 2-mercaptobenzothiazole used in the positive control study.

Definitive Assay

Applied concentration
Weight (g)
Bioguard Tri-Bor
Solutions of test substance
1st induction exposure
100%
5.4682
pure
2nd induction exposure
100%
5.5066
pure
3rd induction exposure
100%
5.0650
pure
Challenge exposure
50%
5.3397
10 mL volumetric flask and swelled with Tween 80 (mL)



Positive Control

Applied concentration
Weight (g)
2-mercaptobenzothiazole
Solutions of test substance
1st induction exposure
50%
5.0015
10 mL volumetric flask swelled with alcohol/water (80:20) 2nd induction exposure 50%
5.0022
10 mL volumetric flask swelled with alcohol/water (80:20) 3rd induction exposure 50%
5.0044
10 mL volumetric flask swelled with alcohol/water (80:20) Challenge exposure 25%
2.5115
10 mL volumetric flask swelled with Acetone

Please let me know if you have any further questions. Thanks.

Fred

Frederick T. Smith
Senior Regulatory Specialist
SciReg, Inc.
12733 Director's Loop
Woodbridge, VA 22192
USA
Phone: (703) 494-6500
Fax: (703) 492-6600
www.SciReg.com

Bioguard Tri-Bor Paste

FOR INDUSTRIAL USE.

NOT FOR HOUSEHOLD USE.

Active Ingredients:

Boron sodium oxide, pentahydrate..... 45%

Boric acid 10%

Zinc borate 5%

Other Ingredients: 40%

TOTAL: 100%

KEEP OUT OF REACH OF CHILDREN

CAUTION

See Side Panel for Additional Precautionary Statements.

EPA Reg. No. 83933-

EPA Est. No. 83933-AUS-001

Preschem Pty. Ltd.
147-149 Herald St.
Cheltenham, 3192, Victoria
Australia

BATCH NO.:

Net Contents:

☐ 44 lbs ☐ 10 lbs ☐ 20.2 oz ☐
☐ 22 lbs ☐ 10.1 oz

FIRST AID	
IF IN EYES	<ul style="list-style-type: none"> Hold eye open and rinse slowly and gently for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a Poison Control Center or doctor for treatment advice.
IF SWALLOWED	<ul style="list-style-type: none"> Call a Poison Control <u>Center</u> or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a Poison Control Center or doctor. Do not give anything to an unconscious person.
IF ON SKIN OR CLOTHING	<ul style="list-style-type: none"> Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a Poison Control Center or doctor for treatment advice.
IN CASE OF EMERGENCY, CALL CHEMTREC AT 800-424-9300. Have the product container or label with you when calling a Poison Control Center or doctor or going for treatment.	
NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.	

April 4, 2013

Bioguard Tri-Bor Paste

DESCRIPTION

Bioguard Tri-Bor Paste has a total of 60% active ingredients for preservation of timber. The paste is a combination of three boron active ingredients, which effectively diffuses through timber. Bioguard Tri-Bor Paste can be used above or below ground in situations where timbers are susceptible to wood-decaying fungi.

Bioguard Tri-Bor Paste is commonly used for groundline treatment of utility poles worldwide, and for other applications such as railroad ties, protection of posts, timber bridges and other timber structures that become susceptible to decay.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling

UTILITY POLES-External Application:

Bulk Paste Application

After inspection, apply Bioguard Tri-Bor Paste with a brush or trowel directly onto the timber. Apply to achieve a layer of no less than 1/16 inch thick to the required distance above and below groundline. Typical applications are from 18 inches to 24 inches below ground to 3 inches above groundline. Ensure paste is pushed into uneven surfaces on the pole such as cracks and checks. Additional below ground coverage may be required where a pole has been exposed near a roadway or hillside. The paste is then covered with a water-proof bandage. If more than one bandage is required, overlap ends to *ensure* complete coverage. Wrap bandage tightly, stapling or nailing to keep it in place. Back fill and tamp soil firmly, but do not fill above the bandage.

Pre-formed Bandage Application

Apply pre-formed Bioguard Tri-Bor bandages directly to the pole surface. No brushing or toweling of paste is required. Unroll a section of bandage and cut to a length approximately 1 inch longer than the circumference of the pole. Remove the thin film from the back of the bandage and wrap the bandage around the pole in the same location as described above for the bulk paste method. The bandage will stick to the pole surface; however, it will require gentle hand pressure to achieve proper adherence before backfilling.

TIMBER STRUCTURES-Internal Application

For control of internal decay, apply Bioguard Tri-Bor Paste into holes where protection is required using the smallest pack size and a grease/caulking gun. Following application, it is important to cap holes with a plug.

RAILROAD TIES-External Application

Apply Bioguard Tri-Bor Paste manually or with a simplified mechanical application machine. Typical applications include the application of the paste under the tie plate to achieve a layer no less than 1/16 inch in thickness. Ensure the paste penetrates uneven surfaces, checks, and the predrilled holes of the spikes or screws that hold the tie plate in place. Minimizing the biological deterioration of wood around anchoring hardware ensures longevity for the tie, reduces loosening of the tie plate, resulting in widening of the rail.

OTHER WOODEN STRUCTURES

Apply paste to area requiring protection from decay using a minimum thickness of 1/16 inch and always ensure a protective bandage is secured over the paste to prevent interference.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION. Causes moderate eye irritation. Harmful if swallowed or if absorbed through skin. Avoid contact with skin, eyes or clothing. Wear goggles, face shield, or safety glasses. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish and wildlife. Do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwaters or rinsate.

PHYSICAL OR CHEMICAL HAZARDS

Do not use or store near heat or open flame.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

PESTICIDE STORAGE: Do not store near open heat or flame.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL: Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available, or puncture and dispose of in sanitary landfill, or by incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

*move
before
Directions*



DATA PACKAGE BEAN SHEET

Date: 14-May-2013

Page 1 of 3

Decision #: 477373

DP #: (411780)

PRIA

Parent DP #:

Submission #: 933363

E-Sub #:

*** Registration Information ***

Registration: 83933-E - BIOGUARD TRI-BOR PASTE

Company: 83933 - PRESICHEM PTY. LTD

Risk Manager:

Risk Manager Reviewer: Thomas Luminello, Jr. TLUMINEL

Sent Date:

PRIA Due Date: 07-Oct-2013

Edited Due Date:

Type of Registration: Product Registration - Section 3

Action Desc: (A540) NEW PRODUCT;NON-FAST TRACK;FIFRA SEC. 2(MM) USES;

Ingredients: See page 3

*** Data Package Information ***

Expedite: ☒ Yes ☐ No

Date Sent: 14-May-2013

Due Back:

DP Ingredient: See page 3

DP Title: Acute Toxicology

CSF Included: ☒ Yes ☐ No

Label Included: ☒ Yes ☐ No

Parent DP #:

Assigned To

Date In

Date Out

Organization: AD / PSB

Last Possible Science Due Date: 07-Sep-2013

Team Name: CTT

Science Due Date:

Reviewer Name:

Chris

5/15/13

Sub Data Package Due Date:

Contractor Name:

*** Studies Sent for Review ***

Printed on Page 2

*** Additional Data Package for this Decision ***

Can be printed on its own page

*** Data Package Instructions ***

New Product Registration: Tri-Bor Paste

TECHNICAL SCREEN DUE DATE: 6/6/2013

Please review the acute tox. 6 pack for completeness

DATA REVIEW

Please review the data for acceptability

DP#: (411780)

*** Studies Sent for Review ***

Decision#: (477373)

MRID	MRID Status	Citation Reference	Guideline	86-5 Status
49096908		Medeiros, M. (2012) Acute Oral Toxicity for Rats: Bioguard Tri-Bor: Final Report. Project Number: 2262/RAA/099/11. Unpublished study prepared by Bioensaïos Analises e Consultoria Ambiental Ltda. 15p.	870.1100/Acute Oral Toxicity	Pass (24-Apr-2013)
49096909		Medeiros, M. (2012) Acute Dermal Toxicity in Rats: Bioguard Tri-Bor: Final Report. Project Number: 2262/RAC/100/11. Unpublished study prepared by Bioensaïos Analises e Consultoria Ambiental Ltda. 13p.	870.1200/Acute dermal toxicity	Pass (24-Apr-2013)
49096910		Smith, F. (2013) Bioguard Tri-Bor Paste: Acute Inhalation Toxicity Waiver Request. Unpublished study prepared by SciReg, Inc. 42p.	870.1300/Acute inhalation toxicity	Pass (24-Apr-2013)
49096911		Medeiros, M. (2012) Acute Eye Irritation / Corrosion in Rabbits: Bioguard Tri-Bor: Final Report. Project Number: 2262/IOP/102/11. Unpublished study prepared by Bioensaïos Analises e Consultoria Ambiental Ltda. 12p.	870.2400/Acute eye irritation	Pass (24-Apr-2013)
49096912		Medeiros, M. (2012) Rabbit Acute Dermal Irritation/Corrosion: Bioguard Tri-Bor: Final Report. Project Number: 2262/ICP/103/11. Unpublished study prepared by Bioensaïos Analises e Consultoria Ambiental Ltda. 12p.	870.2500/Acute dermal irritation	Pass (24-Apr-2013)
49096913		Medeiros, M. (2012) Evaluation of the Skin Sensitisation in Guinea Pigs: Buehler Test Method: Bioguard Tri-Bor: Final Report. Project Number: 2262/SCCMB/101/11. Unpublished study prepared by Bioensaïos Analises e Consultoria Ambiental Ltda. 16p.	870.2600/Skin sensitization	Pass (24-Apr-2013)

DATA PACKAGE BEAN SHEET

Date: 14-May-2013

Page 1 of 3

Decision #: 477373

DP #: (411780)

PRIA

Parent DP #:

Submission #: 933363

E-Sub #:

*** Registration Information ***

Registration: 83933-E - BIOGUARD TRI-BOR PASTE

Company: 83933 - PRESCHEM PTY. LTD

Risk Manager:

Risk Manager Reviewer: Thomas Luminello, Jr. TLUMINEL

Sent Date:

PRIA Due Date: 07-Oct-2013

Edited Due Date:

Type of Registration: Product Registration - Section 3

Action Desc: (A540) NEW PRODUCT;NON-FAST TRACK;FIFRA SEC. 2(MM) USES;

Ingredients: See page 3

*** Data Package Information ***

Expedite: ☒ Yes ☐ No

Date Sent: 14-May-2013

Due Back:

DP Ingredient: See page 3

DP Title: Acute Toxicology

CSF Included: ☒ Yes ☐ No

Label Included: ☒ Yes ☐ No

Parent DP #:

Assigned To

Date In

Date Out

Organization: AD / PSB

Last Possible Science Due Date: 07-Sep-2013

Team Name: CTT

Science Due Date:

Reviewer Name:

Sub Data Package Due Date:

Contractor Name:

*** Studies Sent for Review ***

Printed on Page 2

*** Additional Data Package for this Decision ***

Can be printed on its own page

*** Data Package Instructions ***

New Product Registration: Tri-Bor Paste

TECHNICAL SCREEN DUE DATE: 6/6/2013

Please review the acute tox. 6 pack for completeness

DATA REVIEW

Please review the data for acceptability

MRID	MRID Status	Citation Reference	Guideline	86-5 Status
49096908		Medeiros, M. (2012) Acute Oral Toxicity for Rats: Bioguard Tri-Bor: Final Report. Project Number: 2262/RAA/099/11. Unpublished study prepared by Bioensaïos Analises e Consultoria Ambiental Ltda. 15p.	870.1100/Acute Oral Toxicity	Pass (24-Apr-2013)
49096909		Medeiros, M. (2012) Acute Dermal Toxicity in Rats: Bioguard Tri-Bor: Final Report. Project Number: 2262/RAC/100/11. Unpublished study prepared by Bioensaïos Analises e Consultoria Ambiental Ltda. 13p.	870.1200/Acute dermal toxicity	Pass (24-Apr-2013)
49096910		Smith, F. (2013) Bioguard Tri-Bor Paste: Acute Inhalation Toxicity Waiver Request. Unpublished study prepared by SciReg, Inc. 42p.	870.1300/Acute inhalation toxicity	Pass (24-Apr-2013)
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49096912		Medeiros, M. (2012) Rabbit Acute Dermal Irritation/Corrosion: Bioguard Tri-Bor: Final Report. Project Number: 2262/ICP/103/11. Unpublished study prepared by Bioensaïos Analises e Consultoria Ambiental Ltda. 12p.	870.2500/Acute dermal irritation	Pass (24-Apr-2013)
49096913		Medeiros, M. (2012) Evaluation of the Skin Sensitisation in Guinea Pigs: Buehler Test Method: Bioguard Tri-Bor: Final Report. Project Number: 2262/SCCMB/101/11. Unpublished study prepared by Bioensaïos Analises e Consultoria Ambiental Ltda. 16p.	870.2600/Skin sensitization	Pass (24-Apr-2013)

PRIA 3 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

September 2012

21 Day Screen Start Date: 4-5-13

Experts In-Processing Signature: B. R

Date 4-10-13

Fee Paid: Yes ☒

Division management contacted on issues No ☐ Yes ☐ Date _____

EPA Reg. Number: <u>83933-E</u>		EPA Receipt Date: <u>4-5-13</u>				
Items for Review				Yes	No	N/A*
1	Application Form (EPA Form 8570-1) signed & complete including package type			X		
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4)			X		
	a) All <u>inerts</u> , including fragrances, approved for the proposed uses (see Footnote A)	yes	no			
			X			
3	Certification with Respect to Citation of Data (EPA Form 8570-34) completed and signed (N/A if 100% repack)			X		
	Certificate and data matrix consistent			X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes	no			
	If applicable, is there a letter of Authorization for exclusive use only.					
4	Formulator's Exemption Statement (EPA Form 8570-27) completed and signed (N/A if source is unregistered or applicant owns the technical)			X		
	Data Matrix (EPA Form 8570-35) both internal and external copies (PR 98-5) completed and signed (N/A if 100% repack)			X		
5	a) Selective Method (Fee category experts use)	yes	no			
	b) Cite-All (Fee category experts use)					
	c) Applicant owns all data (Fee category experts use)					
6	5 Copies of Label (Electronic labels on CD are encouraged and guidance is available)			X		
7	Is the data package consistent with PR Notice 86-5			X		
8	Notice of Filing included with petitions					X

9	If applicable for conventional applications, <u>reduced risk rationale</u>				X
	<u>Required Data</u> and/or data waivers. See Footnote C.				
10	a) List study (or studies) not included with application				

Comments: studies passed 11-3 review.

490969

Jacket

Fails

because
of inert

Inerts not approved - see Inert status Form. ←

4/16/13 - I spoke ~~to~~ with the registrant about inert issues and a guideline that was not listed on the data matrix. I informed the registrant that 100% composition was ~~not~~ required for one of the inerts.

4/17/13 - Left message on registrant's voicemail regarding a study deficiency.

- Registrant sent study correction. He also explained that the guideline is not required and a revised CSF was sent, but one inert ~~is~~ is not approved.

4/19/13 - Registrant is still waiting for the supplier to send more information on one of the inerts. When the information comes in, the registrant will send it to the PM.

Draft rejection letter located in the H drive under the ⁴⁷

* N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses or have an application pending with the Agency. If an unapproved inert with no application pending with the Agency is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses or have an application pending with the Agency **even if a product is currently registered** by consulting the [inert Web site](#) and if the inert is not approved nor has an application pending with the Agency, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient**. Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the [Chief of Microbial Pesticides Branch](#).

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Provide the required information necessary to identify an inert approval application that is pending with the Agency; or
3. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;
4. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R300 or R301), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.
3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.

Product ingredient source information may be entitled to confidential treatment

Inert ingredient information may be entitled to confidential treatment

Jackson, Tracy

From: Fred Smith [fsmith@SciReg.com]
Sent: Wednesday, April 17, 2013 2:16 PM
To: Jackson, Tracy
Subject: 83933-E
Attachments: Acute oral tox, page 14.pdf; CSF, 4-17-13.pdf

Tracy—

Attached please find the "best available copy" of page 14 of Volume 9 for Bioguard Tri-Bor Paste (File Symbol 83933-E).

Also attached is a revised CSF. We have requested a letter from the supplier for the composition of [REDACTED] and will provide it as soon as possible.

Relative to the preliminary analysis, Preschem (the registrant) is using EPA-registered sources for two of its three active ingredients in the subject product. The third active ingredient (zinc borate) is currently registered as an end-use product [REDACTED] and is now undergoing registration as an [REDACTED]. As such, preliminary analysis data are not required to be submitted for Bioguard Tri-Bor Paste.

If you have any questions, please let me know. Thank you.

Fred

Frederick T. Smith
Senior Regulatory Specialist
SciReg, Inc.
12733 Director's Loop
Woodbridge, VA 22192
USA
Phone: (703) 494-6500
Fax: (703) 492-6600
www.SciReg.com



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

April 10, 2013

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OPP Decision Number: D-477373
EPA File Symbol or Registration Number: 83933-E
Product Name: BIOGUARD TRI-BOR PASTE
EPA Receipt Date: 05-Apr-2013
EPA Company Number: 83933
Company Name: PRESICHEM PTY. LTD

FREDERICK T. SMITH
SCIREG, INC.
PRESICHEM PTY. LTD
12733 DIRECTOR'S LOOP
WOODBIDGE, VA 22192-

SUBJECT: Receipt of Application and 75% Small Business Waiver Request

Dear Registrant:

The Office of Pesticide Programs has received your application, 75% small business waiver request, and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: A540

NEW PRODUCT;NON-FAST TRACK;FIFRA SEC. 2(MM) USES;

Your request for waiver has been forwarded for review. You will be notified in writing when a determination is made regarding your request. If your waiver request is approved, the decision review time period will start on the date of approval. If your waiver request is denied, you will receive an invoice for the outstanding balance.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-6427.

Sincerely,

A handwritten signature in black ink, appearing to be "m/26".

Front End Processing Staff
Information Technology & Resources Management Division

Fee for Service

✓
{933363(~

This package includes the following

- ☒ New Registration
- ☐ Amendment

☒ Studies? ☒ Fee Waiver?

☐ volpay % Reduction: ____

for Division

- ☒ AD
- ☐ BPPD
- ☐ RD

Risk Mgr. 34

Receipt No.

S-

933363

EPA File Symbol/Reg. No.

83933-E

Pin-Punch Date:

4/5/2013

☐ This item is NOT subject to FFS action.

Action Code:

Requested: A532

Granted: A540

Amount Due: \$ 4631

Parent/Child Decisions:

☒ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: Team 2

Date: 4/9/13

Remarks:

Receipt for Section 3

S: 933363

Resubmission: ☐ Yes ☒ No

Regulatory Type: Product Registration - Section 3

Fee For Service: ☒ Yes ☐ No

Application Type: New Registration

Billable: ☒ Yes ☐ No

Company: 83933 PRESICHEM PTY. LTD V

Risk Manager: Antimicrobials Division, Risk Management Team 34

Product #: 83933-E Product Name: BIOGUARD TRI-BOR PASTE

Override#:

Me Too Section3: Me Too Product Name:

Application Date: 05-Apr-2013

OPP Rec'd Date: 05-Apr-2013

Front End Date: 08-Apr-2013

Risk Manager Send Date:

FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

New registration application

Form A: ☐ Signature Date:

Form B: ☐ Signature Date:

Print Letter

Enter More Information

Tracking

Receipt Content

Study

CSF

View/Edit

New Ingredient Request Date:

New Ingredient Received Date:



United States
Environmental Protection Agency
Washington, DC 20460

☒ Registration
☐ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 83933-	2. EPA Product Manager J. Campbell	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Bioguard Tri-Bor Paste	PM# 34	
5. Name and Address of Applicant (Include ZIP Code) Preschem Pty. Ltd. 147-149 Herald Street Cheltenham, Victoria 3192 Australia <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input checked="" type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Initial application for registration.

PRIA Category: A532

PRIA Fee: \$1,157.75 (after 75% reduction)

Contact: fsmith@SciReg.com

Section - III**1. Material This Product Will Be Packaged In:**

Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input checked="" type="checkbox"/> Other (Specify) cardboard with heat-sealed LDPE liner
* Certification must be submitted			
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) Retail Container 10.1 oz, 20.2 oz, 10 lbs, 22 lbs, 44 lbs	5. Location of Label Directions <input checked="" type="checkbox"/> On label. <input type="checkbox"/> On label accompanying product.	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)

Name Frederick T. Smith	Title Agent	Telephone No. (Include Area Code) (703) 494-6500
----------------------------	----------------	---

Certification

I certify that the statements which I have made on this form and all attachments thereto are true, accurate and complete.
I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature 	3. Title Agent (SciReg, Inc.)	6. Date Application Received (Stamped)
4. Typed Name Frederick T. Smith	5. Date 4/5/13	

56

SciReg, Inc.
Science and Regulatory Consultants

April 5, 2013

Ms. Jacqueline Campbell
Document Processing Desk (APPL)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S. Crystal Dr.
Arlington, VA 22202

Re: New Product Registration Application
Bioguard Tri-Bor Paste
Preschem Pty. Ltd. (Co. No. 83933)

Dear Ms. Campbell:

On behalf of Preschem Pty. Ltd., SciReg, Inc. is submitting a new product registration application for Bioguard Tri-Bor Paste, a remedial wood preservation product for industrial use. This product contains three active ingredients: 1) boron sodium oxide, pentahydrate (PC Code 11110); 2) boric acid (PC Code 11001); and 3) zinc borate (PC Code 128859). The boron sodium oxide, pentahydrate and boric acid are from EPA-registered sources. For zinc borate, [REDACTED]

[REDACTED]

This regulatory action falls under PRIA Category A540: New end use product, FIFRA §2(mm) uses. Preschem qualifies for a 75% PRIA fee reduction. Supporting company and financial documentation are attached, as is their fee payment receipt.

Should you have any questions, please let me know.

Sincerely,



Frederick T. Smith
Senior Regulatory Specialist

Enclosures

TRANSMITTAL DOCUMENT

Submitter

Preschem Pty. Ltd.
147-149 Herald St.
Cheltenham, 3192, Victoria
Australia

SciReg, Inc.*
12733 Director's Loop
Woodbridge, VA 22192

*SciReg, Inc. is the authorized agent for Preschem Pty. Ltd.

Regulatory action in support of which this package is submitted

New Product Registration:
Bioguard Tri-Bor Paste

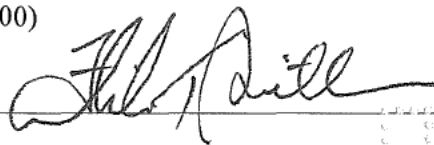
Transmittal Date

April 5, 2013

Contents

- Vol. 1 Administrative Materials
- Vol. 2 Product Identity and Composition, Description of Beginning Materials, Formulation Process, Discussion of Formation of Impurities and Certified Limits (OPPTS 830.1550, 830.1600, 830.1650, 830.1670, 830.1750)
- Vol. 3 Analytical Method (OPPTS 830.1800)
- Vol. 4 Physical-Chemical Properties Summary
- Vol. 5 Physical-Chemical Properties (OPPTS 830.6302, 830.6303, 830.6304)
- Vol. 6 Physical-Chemical Properties (OPPTS 830.7000)
- Vol. 7 Physical-Chemical Properties (OPPTS 830.7200)
- Vol. 8 Physical-Chemical Properties (OPPTS 830.7300)
- Vol. 9 Acute Oral Toxicity (OPPTS 870.1100)
- Vol. 10 Acute Dermal Toxicity (OPPTS 870.1200)
- Vol. 11 Acute Inhalation Toxicity (OPPTS 870.1300)
- Vol. 12 Eye Irritation (OPPTS 870.2400)
- Vol. 13 Dermal Irritation (OPPTS 870.2500)
- Vol. 14 Dermal Sensitization (OPPTS 870.2600)

Company Official: Frederick T. Smith



Company Name: SciReg, Inc.

Company Contact: Frederick T. Smith (703) 494-6500



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.

WASHINGTON, D.C. 20460

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Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number Preschem Pty. Ltd., 147-149 Herald Street, Cheltenham, Victoria 3192, Australia +03 9532 0679	EPA Registration Number/File Symbol 83933
Active Ingredient(s) and/or representative test compounds(s) Boron sodium oxide, pentahydrate; Boric acid; Zinc borate	Date 4/5/13
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Terrestrial non-food; aquatic non-food	Product Name Bioguard Tri-Bor Paste

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data matrix form should be used for this purpose).



I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature

Date

4/5/13

Typed or Printed Name and Title

Frederick T. Smith, Agent (SciReg, Inc.)

A540 - New end use product.

- Must submit or reference Group A and B product chemistry, toxicity, and/or efficacy data for each proposed product.
- Data waivers may be requested. Chemistry data on the TGA in addition to the EP is required if an unregistered source is used.

End Use (EP) or Manufacturing Use (MP) product or Technical Grade of the Active Ingredient (TGA)

Guideline No.	Group A: Product Chemistry Data Study Title	EP Data Submitted	MP Data Submitted	TGA Data Submitted
830.1550	Product Identity & Composition	✓		
830.1600	Description of materials used to produce the product	✓		
830.1650	Description of formulation process	✓		
830.1670	Discussion on the formation of impurities	✓		
830.1700	Preliminary analysis <i>see e-mail Not Required</i>	NA		
830.1750	Certified limits (158.345)	✓		
830.1800	Enforcement analytical method	✓		

Guideline No.	Group B: Product Chemistry Data Study Title	EP Data Submitted	MP Data Submitted	TGA Data Submitted
830.6302	Color	✓		
830.6303	Physical State	✓		
830.6304	Odor	✓		
830.6313	Stability to normal and elevated temperatures metal and metal ions			
830.6314	Oxidation/Reduction (Chemical incompatibility)	NA		
830.6315	Flammability	NA		
830.6316	Explosibility	NA		
830.6317	Storage stability* <i>Study will be submitted</i>			
830.6319	Miscibility	NA		
830.6320	Corrosion Characteristics* <i>Study will be submitted</i>			
830.6321	Dielectric Breakdown Voltage			
830.7000	pH	✓		
830.7050	UV/ Visible Absorption			
830.7100	Viscosity	NA		
830.7200	Melting Point			
830.7220	Boiling Point			
830.7300	Density	✓		
830.7370	Dissociation Constant			
830.7550	Partition Coefficient			
830.7840	Water Solubility			
830.7950	Vapor Pressure			

Grayed out = data not required

*May not be included with initial application

A540 – Acute Toxicity Requirements

New products must either:

- 1) supply the product specific acute toxicity 6 pack data (listed below),
- 2) provide a bridging rationale document or waiver request or,
- 3) use the cite all method of data compensation, if applicable. The bridging document directs OPP to use a currently registered set of 6 acute toxicity data and label; instead of submitting product specific data.

Guideline No.	Acute toxicity (6 pack) Study Title	Cite All	Selective	Waiver Request	Bridging Rational
830.1100	Acute Oral (LD50)	✓			
830.1200	Acute Dermal (LD50)	✓			
830.1300	Acute Inhalation (LC50)	✓			
830.2400	Acute Eye Irritation	✓			
830.2500	Acute Dermal Irritation	✓			
830.2600	Dermal Sensitization	✓			



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
Washington, D.C. 20460

Form Approved OMB No. 2070-0060

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DATA MATRIX

Date <u>4/5/13</u>		EPA Reg No./File Symbol	83933-	Page 1 of 2	
Applicant's/Registrant's Name & Address Preschem Pty. Ltd. 147-149 Herald St. Cheltenham, Victoria 3192 Australia		Product Bioguard Tri-Bor Paste			
Ingredient Boron sodium oxide, pentahydrate; Boric acid; Zinc borate					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.1550	Product identity and composition		Preschem Pty. Ltd.	OWN	Submitted herein
830.1600	Desc. of mat. used to produce the product		Preschem Pty. Ltd.	OWN	Submitted herein
830.1650	Desc. of formulation process		Preschem Pty. Ltd.	OWN	Submitted herein
830.1670	Discussion of formation of impurities		Preschem Pty. Ltd.	OWN	Submitted herein
830.1750	Certified limits		Preschem Pty. Ltd.	OWN	Submitted herein
830.1800	Analytical method		Preschem Pty. Ltd.	OWN	Submitted herein
830.6302	Color		Preschem Pty. Ltd.	OWN	Submitted herein
830.6303	Physical state		Preschem Pty. Ltd.	OWN	Submitted herein
830.6304	Odor		Preschem Pty. Ltd.	OWN	Submitted herein
830.7000	pH		Preschem Pty. Ltd.	OWN	Submitted herein
830.7200	Melting Point		Preschem Pty. Ltd.	OWN	Submitted herein
830.7300	Relative density		Preschem Pty. Ltd.	OWN	Submitted herein
Signature <u><i>Frederick T. Smith</i></u>		Name and Title Frederick T. Smith, Agent		Date <u>4/5/13</u>	



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
Washington, D.C. 20460

Form Approved OMB No. 2070-0060


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DATA MATRIX

Date <u>4/5/13</u>	EPA Reg No./File Symbol <u>83933-</u>	Page <u>2</u> of <u>2</u>
Applicant's/Registrant's Name & Address Preschem Pty. Ltd. 147-149 Herald St. Cheltenham, Victoria 3192 Australia	Product Bioguard Tri-Bor Paste	

Ingredient Boron sodium oxide, pentahydrate; Boric acid; Zinc borate

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.1100	Acute oral toxicity		Preschem Pty. Ltd.	OWN	Submitted herein
870.1200	Acute dermal toxicity		Preschem Pty. Ltd.	OWN	Submitted herein
870.1300	Acute inhalation toxicity waiver request		Preschem Pty. Ltd.	OWN	Submitted herein
870.2400	Primary eye irritation		Preschem Pty. Ltd.	OWN	Submitted herein
870.2500	Primary dermal irritation		Preschem Pty. Ltd.	OWN	Submitted herein
870.2600	Dermal sensitization		Preschem Pty. Ltd.	OWN	Submitted herein

Signature 	Name and Title Frederick T. Smith, Agent	Date <u>4/5/13</u>
---	---	-----------------------



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
Washington, D.C. 20460

Form Approved OMB No. 2070-0060

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DATA MATRIX

Date <u>4/5/13</u>	EPA Reg No./File Symbol	83933-	Page 1 of 2		
Applicant's/Registrant's Name & Address Preschem Pty. Ltd. 147-149 Herald St. Cheltenham, Victoria 3192 Australia		Product Bioguard Tri-Bor Paste			
Ingredient Boron sodium oxide, pentahydrate; Boric acid; Zinc borate					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Preschem Pty. Ltd.	OWN	Submitted herein
			Preschem Pty. Ltd.	OWN	Submitted herein
			Preschem Pty. Ltd.	OWN	Submitted herein
			Preschem Pty. Ltd.	OWN	Submitted herein
			Preschem Pty. Ltd.	OWN	Submitted herein
			Preschem Pty. Ltd.	OWN	Submitted herein
			Preschem Pty. Ltd.	OWN	Submitted herein
			Preschem Pty. Ltd.	OWN	Submitted herein
			Preschem Pty. Ltd.	OWN	Submitted herein
			Preschem Pty. Ltd.	OWN	Submitted herein
			Preschem Pty. Ltd.	OWN	Submitted herein
			Preschem Pty. Ltd.	OWN	Submitted herein
Signature <u>Frederick T. Smith</u>			Name and Title Frederick T. Smith, Agent		Date <u>4/5/13</u>



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
Washington, D.C. 20460

Form Approved OMB No. 2070-0060

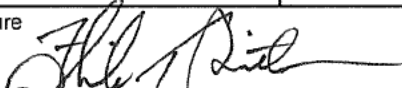
Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date <u>4/5/13</u>	EPA Reg No./File Symbol 83933-	Page 2 of 2
Applicant's/Registrant's Name & Address Preschem Pty. Ltd. 147-149 Herald St. Cheltenham, Victoria 3192 Australia	Product Bioguard Tri-Bor Paste	

Ingredient Boron sodium oxide, pentahydrate; Boric acid; Zinc borate

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Preschem Pty. Ltd.	OWN	Submitted herein
			Preschem Pty. Ltd.	OWN	Submitted herein
			Preschem Pty. Ltd.	OWN	Submitted herein
			Preschem Pty. Ltd.	OWN	Submitted herein
			Preschem Pty. Ltd.	OWN	Submitted herein
			Preschem Pty. Ltd.	OWN	Submitted herein

Signature 	Name and Title Frederick T. Smith, Agent	Date <u>4/5/13</u>
---	---	-----------------------



Preschem Pty Ltd
ABN 41 314599336

Office and Manufacturing
147- 149 Herald Street
Cheltenham, Victoria 3192
Telephone: 03 9532 0679
Facsimile: 03 9532 1041
International: 61+3
Email: office@preschem.com
Web: www.preschem.com

17th January, 2013

Document Processing Desk
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S. Crystal Dr.
Arlington, VA 22202

Re: Authorized Agent

To Whom It May Concern:

This letter serves to inform the Agency that Preschem Pty. Ltd.'s (EPA Company No.83933) authorized agent is:

SciReg, Inc.
12733 Director's Loop
Woodbridge, VA 22192
Phone (703) 494-6500
Fax (703) 492-6600

All correspondence should be sent directly to SciReg. This is effective immediately.

Should you have any questions, please call me on +61 3 9532 0679.

Sincerely,

Rohan Baker
Production Manager

cc: SciReg, Inc.

"Manufacturers of Wood Preservatives and Clear Timber Finishes"

Bioguard Tri-Bor Paste

FOR INDUSTRIAL USE.

NOT FOR HOUSEHOLD USE.

FIRST AID	
IF IN EYES	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently for 15-20 minutes.• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.• Call a Poison Control Center or doctor for treatment advice.
IF SWALLOWED	<ul style="list-style-type: none">• Call a Poison Control Centre or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to do so by a Poison Control Center or doctor.• Do not give anything to an unconscious person.
IF ON SKIN OR CLOTHING	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.• Call a Poison Control Center or doctor for treatment advice.
IN CASE OF EMERGENCY, CALL CHEMTREC AT 800-424-9300. Have the product container or label with you when calling a Poison Control Center or doctor or going for treatment.	
NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.	

Active Ingredients:

Boron sodium oxide, pentahydrate..... 45%

Boric acid 10%

Zinc borate 5%

Other Ingredients: 40%

TOTAL: 100%

KEEP OUT OF REACH OF CHILDREN

CAUTION

See Side Panel for Additional Precautionary Statements.

EPA Reg. No. 83933-

EPA Est. No. 83933-AUS-001

Preschem Pty. Ltd.
147-149 Herald St.
Cheltenham, 3192, Victoria
Australia

BATCH NO.:

Net Contents:

☐ 44 lbs ☐ 10 lbs ☐ 20.2 oz ☐
☐ 22 lbs ☐ 10.1 oz

April 4, 2013

Bioguard Tri-Bor Paste

DESCRIPTION

Bioguard Tri-Bor Paste has a total of 60% active ingredients for preservation of timber. The paste is a combination of three boron active ingredients, which effectively diffuses through timber. Bioguard Tri-Bor Paste can be used above or below ground in situations where timbers are susceptible to wood-decaying fungi.

Bioguard Tri-Bor Paste is commonly used for groundline treatment of utility poles worldwide, and for other applications such as railroad ties, protection of posts, timber bridges and other timber structures that become susceptible to decay.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling

UTILITY POLES-External Application:

Bulk Paste Application

After inspection, apply Bioguard Tri-Bor Paste with a brush or trowel directly onto the timber. Apply to achieve a layer of no less than 1/16 inch thick to the required distance above and below groundline. Typical applications are from 18 inches to 24 inches below ground to 3 inches above groundline. Ensure paste is pushed into uneven surfaces on the pole such as cracks and checks. Additional below ground coverage may be required where a pole has been exposed near a roadway or hillside. The paste is then covered with a water-proof bandage. If more than one bandage is required, overlap ends to insure complete coverage. Wrap bandage tightly, stapling or nailing to keep it in place. Back fill and tamp soil firmly, but do not fill above the bandage.

Pre-formed Bandage Application

Apply pre-formed Bioguard Tri-Bor bandages directly to the pole surface. No brushing or toweling of paste is required. Unroll a section of bandage and cut to a length approximately 1 inch longer than the circumference of the pole. Remove the thin film from the back of the bandage and wrap the bandage around the pole in the same location as described above for the bulk paste method. The bandage will stick to the pole surface; however, it will require gentle hand pressure to achieve proper adherence before backfilling.

TIMBER STRUCTURES-Internal Application

For control of internal decay, apply Bioguard Tri-Bor Paste into holes where protection is required using the smallest pack size and a grease/caulking gun. Following application, it is important to cap holes with a plug.

RAILROAD TIES-External Application

Apply Bioguard Tri-Bor Paste manually or with a simplified mechanical application machine. Typical applications include the application of the paste under the tie plate to achieve a layer no less than 1/16 inch in thickness. Ensure the paste penetrates uneven surfaces, checks, and the predrilled holes of the spikes or screws that hold the tie plate in place. Minimizing the biological deterioration of wood around anchoring hardware ensures longevity for the tie, reduces loosening of the tie plate, resulting in widening of the rail.

OTHER WOODEN STRUCTURES

Apply paste to area requiring protection from decay using a minimum thickness of 1/16 inch and always ensure a protective bandage is secured over the paste to prevent interference.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION. Causes moderate eye irritation. Harmful if swallowed or if absorbed through skin. Avoid contact with skin, eyes or clothing. Wear goggles, face shield, or safety glasses. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish and wildlife. Do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwaters or rinsate.

PHYSICAL OR CHEMICAL HAZARDS

Do not use or store near heat or open flame.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

PESTICIDE STORAGE: Do not store near open heat or flame.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL: Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available, or puncture and dispose of in sanitary landfill, or by incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

